

Medicare Coverage & Payment For New Technologies

Overview

Understanding Medicare coverage and payment policy is critical to the successful launch of any new life sciences technology. Foley Hoag's Medicare Coverage & Payment Practice provides regulatory and legislative advice to a broad array of leading life sciences companies, including:

- global pharmaceutical and biotechnology firms,
- trade associations,
- venture capital and investment funds,
- patient associations and advocacy groups, and
- early-stage companies.

In close collaboration with our clients, we work with senior agency officials, Members of Congress, congressional staff, patient advocates, and healthcare experts to shape agency interpretations, clarify regulatory guidance, and address novel payment issues. Our attorneys and health policy specialists have served as Democratic and Republican Congressional staff and in senior decision-making roles at the Centers for Medicare & Medicaid Services (CMS) and at local Medicare contractors.

Government spending accounts for nearly one-half of the nation's health expenditures, and Medicare policy decisions have widespread impact on private sector medical coverage and payment. Medicare and other payers are in the middle of a transformation toward evidence-based medicine that rewards value and improved health outcomes. In this new environment, it is critical for companies to develop clinical evidence to support timely, widespread coverage and reimbursement for new technologies. Foley Hoag has deep expertise in working with public and private payers on innovative products and therapies. Our strategy combines convincing legal arguments with a rich understanding of the clinical evidence necessary for widespread adoption and utilization of new products.

Comprehensive Regulatory Strategy

Over the course of nearly two decades of experience with CMS, Congress, Medicare contractors, and FDA we have developed the reputation and relationships necessary to achieve our clients' goals at the most appropriate decision-making level. This extensive background informs our strategies to obtain appropriate coverage and payment for a wide range of life sciences products and services, including drugs, biologics, medical devices and durable medical equipment, laboratory technology, and molecular diagnostics.

Our attorneys regularly represent clients before CMS and Medicare contractors. We have helped shape federal policies and programs through formal administrative processes, informed by our deep experience with the regulatory system.

Patient access and appropriate reimbursement depend on addressing four major elements: coverage, payment, coding, and billing. Each presents potential risks for companies introducing new technology into the healthcare marketplace. The Foley Hoag Coverage & Payment team works closely with our clients to address each aspect of the Medicare process:

- Building a strong clinical case for coverage, particularly in medical environments characterized by competition or small patient populations. We work with companies to develop the most compelling clinical story, to identify the best audience at CMS and the contractors, and to prepare the best presentation of new technology, often involving expert physicians in the process.
- Obtaining and using appropriate permanent, temporary, and unlisted HCPCS and CPT codes to describe new technology. Effective coding must be coordinated with coverage and payment strategies.

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- Identifying billing issues that may come up at multiple sites of care, when legacy Medicare regulations may have unanticipated effects on new business models.
- Working with payers to establish payment rates that enhance patient access. Both CMS and the contractors play important roles in setting rates, and the most effective strategies often involve coordination of many stakeholders, including innovator companies, physicians, and patient groups.

Our Experience

In recent years, we have:

- Advised a coalition of leading academic medical centers and medical device manufacturers in helping CMS design and implement one of the first data registries in its Coverage with Evidence Development program.
- Developed novel legal arguments and assembled compelling scientific evidence to secure appropriate coding and payment for biotechnology products.
- Advised numerous molecular diagnostic companies on the current Medicare coverage, payment, and billing framework.
- Represented a leading cancer center in obtaining a DRG reclassification for hospital inpatient reimbursement for an anti-cancer therapy for renal cell carcinoma and melanoma.
- Coordinated physician and professional society advocacy in an effort to revise restrictive local coverage policies for a new drug.

Federal Legislative Advocacy

As part of our comprehensive approach to problem-solving, Foley Hoag provides our clients with guidance on Medicare payment policy legislation and Congressional oversight. Each Congress makes numerous changes to Medicare payment rules for medical technology that can impact new product launches. Many new products present novel reimbursement challenges that cannot be addressed through current regulatory frameworks. These issues have particular relevancy in anticipation of comprehensive health reform legislation in 2009 that could include dramatic changes to hospital and physician payment policy.

Our attorneys draw upon a wealth of experience with congressional advocacy to identify the most effective strategy for solving the problem at hand. One of the unique challenges of this kind of work is coordinating the efforts at CMS with advocacy on Capitol Hill. Our lawyers provide a comprehensive range of legal and legislative services, including preparing draft legislation and congressional testimony, analyzing pending legislation and proposed rules, and working with congressional staff to track and influence complex legislation.

Our legislative experience reaches nearly every aspect of federal healthcare policy, with a focus on coverage and payment issues. Our work has included advocacy on:

- Development and passage of the Medicare Prescription Drug Benefit,
- Expansion of Medicare Part B payment for drugs that are not usually self-administered,
- Additional payments for new devices under “New Technology” rules,
- Statutory rules for classification and payment of radiopharmaceuticals,
- Creation of a new center within HHS to support development of advanced technology for pandemic flu and biodefense preparedness, and
- Comparative effectiveness research funding and implementation.